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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/943,080	08/30/2001	Carlo Effenhauser	RDID01056US	7687
41577	7590	09/14/2006	EXAMINER	
WOODARD, EMHARDT, MORIARTY, MCNETT & HENRY LLP 111 MONUMENT CIRCLE, SUITE 3700 INDIANAPOLIS, IN 46204-5137			SZMAL, BRIAN SCOTT	
			ART UNIT	PAPER NUMBER
			3736	

DATE MAILED: 09/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/943,080

Applicant(s)

EFFENHAUSER ET AL.

Examiner

Brian Szmaj

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-17 and 20-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 24-40 is/are allowed.
- 6) ☒ Claim(s) 13-17 and 20-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 21 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The current specification discloses a capillary channel but does not disclose the shape of the capillary channel, and therefore, the particular shape of the capillary channel cannot be claimed.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 13-17, 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garcia et al (4,637,403) in view of Yassinzadeh et al (5,700,695).

Garcia et al disclose a glucose monitoring system and further disclose a drive unit having a holder, wherein the holder is moved from a first position into a second position when the drive unit is activated; a disposable lancing unit which has a holding area that

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is removably positioned in the holder; an elongate capillary structure, wherein the proximal end of the capillary structure comprises at least one capillary channel for transporting body fluid connected to the holding area; a distal end of the capillary structure defining a tip which is suitable for piercing skin, wherein the distal end of the capillary structure is located outside the skin when the holder is arranged in the first position and inserted into the skin up to a puncture depth in the second position; wherein the drive unit moves the lancing device such that after the lancing device reaches the second position, the lancing device is moved back into a collecting position, such that in the collecting position a section of the capillary structure located in the skin is shorter than the section of the capillary structure when the lancing device is in the second position; the holding area has a detection zone for detecting at least one analyte, the detection zone being arranged such that the detection zone can take up body fluid from the capillary structure; the drive unit moves the lancing unit in such a manner that the lancing unit remains in the second position for a time interval and subsequently, the lancing unit is moved into a position in which the distal end of the capillary structure is outside the skin; and the capillary structure and holding area are integrally connected. See Column 9, lines 41-66; Column 10, lines 50-55; Column 12, lines 15-21.

Garcia et al however fail to disclose the at least one capillary channel is open to the outside in an area which comprises at least a part of the longitudinal extension of the capillary structure extending beyond the distal end; the area of the capillary structure that is open to the outside has a channel shape; and the length of the capillary structure

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is in the range from 0.3-3.0 mm and the cross-section of the capillary structure is in the range of 0.03-0.8 mm.

Yassinzadeh et al, as discussed above, disclose a lancing device and further disclose the at least one capillary channel is open to the outside in an area which comprises at least a part of the longitudinal extension of the capillary structure extending beyond the distal end; the area of the capillary structure that is open to the outside has a channel shape; and the length of the capillary structure is in the range from 0.3-3.0 mm and the cross-section of the capillary structure is in the range of 0.03-0.8 mm. See Figures 2, 3 and 8; Column 4, lines 6-46 and 64-67; and Column 5, lines 1-6.

Since both Garcia et al and Yassinzadeh et al disclose lancing devices, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the lancet of Garcia et al, to include the use of an open capillary channel, as per the teachings of Yassinzadeh et al, since it would provide an alternative means of drawing blood into the holding area for testing.

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have the open channel of the capillary structure from the distal end to the proximal end because the Applicant has not disclosed that the open channel from the distal end to the proximal end provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Yassinzadeh et al's lancing device, and the Applicant's invention to perform equally well with either the open channel as taught by Yassinzadeh et al or the claimed open channel in Claim 14 because both

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open channels would perform the same function of drawing a blood sample from the sample site through the use of capillary action.

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have the open channel of the capillary structure have an essentially rectangular-shaped cross-section because the Applicant has not disclosed that the cross-sectional shape of the capillary channel provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Yassinzadeh et al's capillary channel, and the Applicant's invention to perform equally well with either the cross-sectional shape as taught by Yassinzadeh et al or the claimed rectangular-shaped cross-section in Claim 21 because both capillary channels would perform the same function of drawing a blood sample from the sample site through the use of capillary action.

5. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Garcia et al (4,637,403) and Yassinzadeh et al (5,700,695) as applied to claim 13 above, and further in view of Mauze et al (6,375,627 B1).

Garcia et al and Yassinzadeh et al, as discussed above, disclose a lancing system but fail to disclose the holding area and the capillary structure are made from silicon.

Mauze et al disclose a lancing system and further disclose a lancing system but fail to disclose the holding area and the capillary structure are made from silicon. See Column 6, lines 54-56.

Since Garcia et al, Yassinzadeh et al, and Mauze et al disclose lancing systems, one of ordinary skill in the art at the time the invention was made to modify the combination of

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Garcia et al and Yassinzadeh et al, to make the lancing element of silicon, as per the teachings of Mauze et al, since it is well known in the art to utilize silicon for a lancing material.

Allowable Subject Matter

6. The following is a statement of reasons for the indication of allowable subject matter: Claims 24-40 contain allowable subject matter, in particular, a capillary groove for drawing the body fluid from the incision to the detections zone via capillary action, as claimed in Claim 24; and a capillary groove for transporting the body fluid via capillary action to the detection zone, as claimed in Claim 34.

Response to Arguments

7. Applicant's arguments, filed July 20, 2006, with respect to Claims 24-33 have been fully considered and are persuasive. The rejection of Claims 24-33 under Garcia et al (4,637,403), Yassinzadeh et al (5,700,695), Ramel (5,540,709) and Eriksen (2,359,550) has been withdrawn.

8. Applicant's arguments filed July 20, 2006 have been fully considered but they are not persuasive. Regarding Claims 13-17 and 20-23, the Applicants argue Yassinzadeh et al fail to disclose the needle being capable of drawing a sample via capillary action. Yassinzadeh et al clearly disclose the open distal end of the needle structure being capable of drawing a sample from the surrounding tissue in Column 5, lines 3-6, which would constitute the initial use of capillary action to draw the fluid sample to the lumen.

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Current Claim 13 only requires a capillary channel that is capable of transporting body fluid to a holding area, and does not disclose how the fluid is transported to the holding area.

9. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., transporting the fluid sample via the capillary channel to the holding area via capillary action) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmaj whose telephone number is (571) 272-4733. The examiner can normally be reached on Monday-Thursday, with Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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